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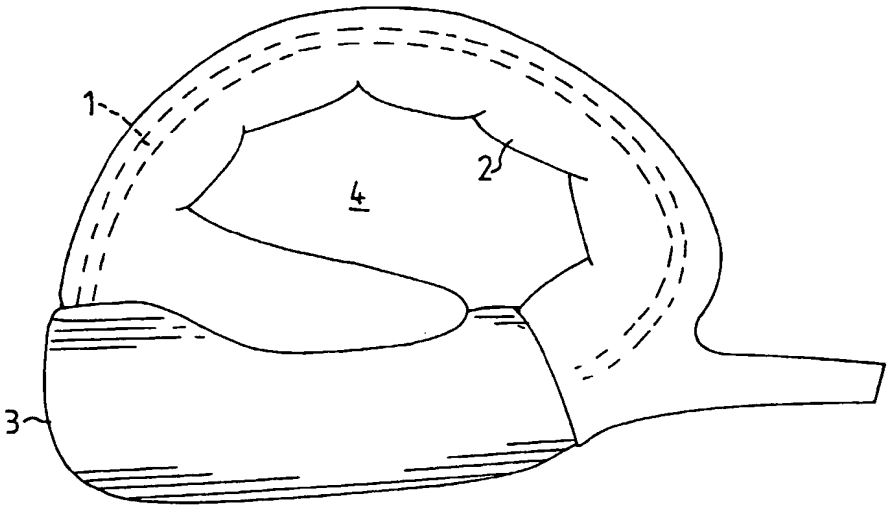
(54) Title: APPARATUS FOR GENTLE FORMING OF STOMA OPENING




(57) **Abstract:** An apparatus for forming a stoma opening in the stomach or oesophagus of a patient includes a constriction device (1,3) applied on the patient's stomach or oesophagus. The constriction device includes an elongate adjustable constriction member (1) extending in a loop around and constricting the stomach or oesophagus to form the stoma opening therein and an adjustment device that adjusts the longitudinal extension of the constriction member to change the size of the stoma opening. A layer (2) of a soft viscoelastic material extends between the constriction device (1,3) and the patient's stomach or oesophagus, to protect the stomach or oesophagus from being eroded by the constriction device. The soft layer (2) has an inwardly directed radial extension in said loop such that when the adjustment device is operated to decrease the longitudinal extension of the constriction member (1), the layer is forced to expand radially inwardly in said loop causing a corresponding decrease in the size of the stoma opening.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

# APPARATUS FOR GENTLE FORMING OF STOMA OPENING

The present invention relates to an apparatus for forming a stoma opening in the stomach or oesophagus of a patient. The apparatus comprises a constriction device adapted to be applied on the patient's stomach or oesophagus, the constriction device including an elongate adjustable constriction member adapted to extend in a loop around and constrict the stomach or oesophagus to form the stoma opening therein, an adjustment device that adjusts the longitudinal extension of the constriction member in said loop to change the size of the stoma opening, and a layer of a soft material applied on the constriction device.

This kind of apparatus in the form of a gastric banding device, in which a band encircles a portion of a patient's stomach to restrict the food intake of the patient, have been used in surgery for morbid obesity to form a small gastric pouch above the band and a reduced stoma opening in the stomach. Although such a band is applied around the stomach to obtain an optimal stoma opening during surgery, some prior gastric banding devices are provided with an adjustment device enabling a minor post-operation adjustment of the size of the stoma opening. In all such prior art devices, such as disclosed in U.S. Patent No. 4 592 339, European Patent No. 0611561 and International Patent Application WO 94/27504, the adjustment device typically comprises an inflatable cavity in the band and an injection port in fluid connection with the inflatable cavity. The injection port is subcutaneously implanted to allow the addition of fluid to or withdrawal of fluid from the cavity by an injection needle penetrating the patient's skin and passing into the injection port. In practice, the band is made of silicone, which is a material approved for implantation, and the fluid is a liquid such as an isotonic salt solution mixed with other conventional materials.

Since the salt solution is an incompressible liquid the pressure will be the same in the entire cavity of the prior band. In consequence, the entire silicone band will press relatively hard against the stomach when salt solution is added to decrease the stoma opening, which may be injurious to the stomach.

The kind of apparatus presented initially has also been used for treating heartburn and reflux disease due to hiatal hernia, *i.e.* a portion of the stomach immediately below the gastric fundus slides upwardly through the oesophageal hiatus. In consequence, stomach acids and foods are regurgitated into the oesophagus. In the late 1970s a prior art prosthesis called Angelchik, according to U.S. Patent No. 3 875 928, was used to operatively treat heartburn and reflux disease. However, the Angelchik prosthesis had a major disadvantage in that it was not possible to adjust the size of the restriction opening after the operation. A further disadvantage was that the prosthesis did not satisfactorily protect the oesophagus and the surrounding area against injuries due to poor shape of the prosthesis. Therefore, operations using the Angelchik prosthesis are no longer practised.

An operation technique, semi-fundoduplicatio, is currently in use for treating heartburn and reflux disease. A most common operation is Nissen semi-fundoduplicatio, in which one takes the fundus of the stomach and makes a three quarter of a turn around the oesophagus and sutures between the stomach and oesophagus. Although this operation works fairly well it has three main disadvantages. Firstly, most patients treated in accordance to semi-fundoduplicatio lose their ability to belch. Secondly, many of these patients get dysphasia, *i.e.* difficulties to swallow after the operation. Thirdly, it is not possible to adjust the stoma opening in the oesophagus or stomach in any way after the operation. Characteristic for these patients is the variation of their problems over the day. For example, many patients have difficulties during the night when they lie down because of stomach acid leaking up into the oesophagus.

WO 01/47435 A2 discloses an adjustable constriction device for constricting the oesophagus, in order to treat heartburn and reflux disease. The known constriction device is embedded in soft silicone.

The prime object of the present invention is to provide a new adjustable apparatus designed to carefully form a stoma opening in the stomach or oesophagus of a patient, wherein the new apparatus is suited for treating obese patients as well as patients suffering from heartburn and reflux disease.

Another object of the present invention is to provide a new convenient apparatus for

forming a stoma opening, which is capable of carefully adjusting the size of the stoma opening without risking injuring the stomach or oesophagus.

These objects are achieved by an apparatus of the kind described initially characterised in that the layer is a viscoelastic material and extends between the constriction device and the patient's stomach or oesophagus, when the constriction device is implanted, to protect the stomach or oesophagus from being eroded by the constriction device, and that the layer of viscoelastic material has an inwardly directed radial extension in said loop of the constriction member such that when the adjustment device is operated to decrease the longitudinal extension of the constriction member the layer of viscoelastic material is forced to expand radially inwardly in said loop causing a corresponding decrease in the size of the stoma opening.

This results in the important advantage that it is not the constriction member itself, usually made of a relatively hard silicone material, that directly abut and press against the stomach or oesophagus when the size of the stoma opening is further decreased, as is the case for prior gastric banding devices. Rather, it is the layer of viscoelastic material that carefully abuts and presses against the stomach or oesophagus as it is expanded inwardly in the loop.

Another important advantage achieved by the present invention is that, depending on the thickness of the layer of viscoelastic material, a relatively small change in the longitudinal extension of the constriction member made by the adjustment device may result in a relatively large change in the size of the stoma opening.

For example, the viscoelastic material may comprise a foam or gel of polymer.

Advantageously, the layer of viscoelastic material completely covers the elongate constriction member and is divided into a series of separate elongate cells of viscoelastic material distributed around the elongate constriction member. As a result, the viscoelastic material located on the inner side of said loop formed by the elongate constriction member is prevented from flowing to the outer side of said loop when the constriction device is adjusted to reduce the stoma opening.

Generally, the adjustment device comprises a powered adjustment device, for example including a motor, preferably an electric motor. The apparatus may comprise an implantable energy-transforming device adapted to transform wireless energy emitted from outside the patient's body into an energy form suited for powering the adjustment device. Such an energy form may be electric energy for powering an electric motor of the adjustment device.

To conveniently adjust the size of the stoma opening the apparatus may comprise a wireless remote control for controlling the adjustment device from outside the patient's body to adjust the constriction device to change the size of the stoma opening.

In accordance with an embodiment of the invention the constriction member comprises a hydraulic constriction member, typically with an inflatable cavity, and the adjustment device comprises a pump hydraulically connected to the hydraulic constriction device.

In a preferred simple mechanical embodiment of the invention, the constriction member is non-inflatable and comprises a main portion and two elongated end portions. The adjustment device is adapted to establish longitudinal relative displacement between the end portions of the constriction member, such that the size of the stoma opening is adjusted. Since a relatively small change in the longitudinal extension of the constriction member may result in a relatively large change in the size of the stoma opening, the adjustment device may be designed very simple, because the necessary stroke of the displacement between the end portions of the constriction member can be very short.

The adjustment device suitably comprises a movement transferring member in engagement with at least one of the end portions of the constriction member and operable to displace said one end portion relative to the other end portion of the constriction member. The movement-transferring member may comprise a gear wheel fixed to said other end portion of the constriction member and a gear rack formed on said one end portion of the constriction member, the gear wheel and the gear rack being in mesh with each other. A motor may be connected to the gear wheel and a worm gear may be connected between the motor and the gear wheel. The motor, worm gear, gear wheel and

gear rack are suitably contained in a rigid housing that may be at least in part covered with the layer of soft viscoelastic material to protect the stomach or oesophagus.

In the enclosed drawings:

Figure 1 is a view of an apparatus according to an embodiment of the present invention having a mechanical constriction member in a non-constricted state;

Figure 2 is a view of the apparatus of Figure 1 with the constriction member in a constricted state;

Figure 3 is a schematic sectional view of the embodiment shown in Figure 1;

Figure 4 illustrates the apparatus according to Figures 1 and 2 implanted in an obese patient; and

Figure 5 is a cross-section of a mechanical constriction device according to another embodiment of the invention.

Figure 1 shows a constriction device of an apparatus of the present invention including an elongated constriction member in the form of a flexible plastic band 1 and a protective layer 2 of a viscoelastic material, such as silicone having hardness less than 20 Shore, applied on the band 1, so that the band 1 is embedded in the protective layer 2. Two end portions of the band 1 are connected to an elongate housing 3 containing an adjustment device, which is capable of establishing longitudinal relative displacement between the end portions. The band 1 and the housing 3 form a closed loop defining a restriction opening 4. Figure 1 illustrates the apparatus when the restriction opening 4 is relatively large, whereas Figure 2 illustrates the apparatus when the adjustment device has been operated to pull the end portions together causing the viscoelastic material of the layer 2 to expand inwardly in the loop, so that the restriction opening 4 is reduced. When the constriction device is implanted in a patient, the size of the stoma opening formed in the patient's stomach corresponds to the size of the restriction opening 4.

With reference to Figure 3, the adjustment device 5 will be described in more detail. The band 1 has a first end portion 6 releasably connected to the housing 3 and a second

end portion 7 connected to the adjustment device 5. The adjustment device 5 includes an electric motor 8 and a movement transferring means 9 in engagement with the end portion 7. The electric motor 8 operates the movement transferring means 9 to displace the end portion 7 relative to portion 6 in the loop formed by the band 1 and housing 3. The movement transferring means 9 includes a gear wheel 10 fixed to the housing 3, a worm gear 11 connected between the electric motor 8 and the gear wheel 10, and a gear rack 12 formed on the end portion 7, wherein the gear wheel 10 and the gear rack 12 are in mesh with each other.

Figure 4 illustrates the constriction device the embodiment shown in Figures 1 and 2 applied on the stomach 18 of an obese patient. The band 1 and housing 3 of the constriction device extend in a loop around and constricts the stomach 18 to form an upper pouch 19 of the stomach 18 and a restricted stoma opening in the stomach 18. A rechargeable electric power supply 13 is implanted in the patient and fixed to the breastbone 14 (the sternum). An external remote control 15 controls the adjustment device 5 and transmits signals that are received by a combined control and energy transforming unit 16 subcutaneously implanted in the patient. The unit 16 is electrically connected to the electric power supply 13 and transforms the energy of the signals into an electric current that is used for charging the electric power supply 13. For example, the signals may include electromagnetic waves and the unit 16 may include an electric p-n junction element that transforms the wireless energy into an electric current. A resilient insulated electric wire 17 connects the power supply 13 and the electric motor 8 in the housing 3. The electric wire 17 extends helically between the power supply 13 and housing 3, in order to permit the electric wire 17 to be temporarily extended when dynamic movements of the stomach 18 and oesophagus occur, so that the risk of breaking the electric wire 17 is eliminated.

Figure 5 shows a cross-section of a mechanical constriction device of another embodiment of the invention, comprising a double walled tubing 20, an external wall 21 and an internal wall 22 spaced from the external wall 21. The tubing 20 has partition walls 23 dividing the space between the external and internal walls 21 and 22, respectively, of

the tubing 20 into longitudinal cells 24, which are filled with a soft viscoelastic material, such as a gel. A constriction member in the form of a strong band 25 of nylon or the like slides in the tubing 20 to enable adjustment of the constriction device. One cell 24A is larger than the other cells 24 and intended to abut against the stomach or oesophagus when the constriction device form a loop around the stomach or oesophagus. As a result, when the constriction device is adjusted to reduce the stoma opening, the viscoelastic material located in cell 24A is prevented from flowing to the cells 24 that will be located more or less on the outer side of said loop that does not contact the stomach or oesophagus.

## CLAIMS

1. An apparatus for forming a stoma opening in the stomach (18) or oesophagus of a patient, the apparatus comprising a constriction device (1,3) adapted to be applied on the patient's stomach or oesophagus, the constriction device including an elongate adjustable constriction member (1) adapted to extend in a loop around and constrict the stomach or oesophagus to form the stoma opening therein, an adjustment device (5) that adjusts the longitudinal extension of the constriction member (1) in said loop to change the size of the stoma opening, and a layer (2) of a soft material applied on the constriction device (1,3), **characterised** in that the layer (2) is a viscoelastic material and extends at least between the constriction device (1,3) and the patient's stomach (18) or oesophagus, when the constriction device is implanted, to protect the stomach or oesophagus from being eroded by the constriction device, and that the layer (2) of viscoelastic material has an inwardly directed radial extension in said loop such that when the adjustment device is operated to decrease the longitudinal extension of the constriction member (1), the layer (2) of viscoelastic material is forced to expand radially inwardly in said loop causing a corresponding decrease in the size of the stoma opening.

2. An apparatus according to claim 1, wherein the viscoelastic material comprises a foam or gel.

3. An apparatus according to claim 1 or 2, wherein the layer of viscoelastic material completely covers the elongate constriction member (1) and is divided into a series of separate elongate cells of viscoelastic material distributed around the elongate constriction member (1).

4. An apparatus according to claim 3, wherein the constriction member (1) is non-inflatable.

5. An apparatus according to claim 4, wherein the constriction member (1) comprises a main portion and two elongated end portions (6,7), and the adjustment device (5) establishes longitudinal relative displacement between the end portions of the constriction member, such that the size of the stoma opening is adjusted.

6. An apparatus according to claim 5, wherein the adjustment device (5) comprises a movement transferring means (9) in engagement with at least one of the end portions (6,7) of the constriction member (1) and operable to displace said one end portion (7) relative to the other end portion (6) of the constriction member.

7. An apparatus according to claim 6, wherein the movement transferring means (9) comprises a gear wheel (10) fixed to said other end portion (6) of the constriction member (1) and a gear rack (12) formed on said one end portion (7) of the constriction member, the gear wheel and the gear rack being in mesh with each other.

8. An apparatus according to claim 7, wherein the adjustment device (5) comprises a motor (8) connected to the gear wheel (10).

9. An apparatus according to claim 8, wherein the adjustment device (5) comprises a worm gear (11) connected between the motor (8) and the gear wheel (10).

10. An apparatus according to any of claims 1-9, further comprising a rigid housing containing the adjustment device (5).

11. An apparatus according to any of claims 1-4, wherein the adjustment device (5) comprises a motor (8).

12. An apparatus according to any of claims 1-3, wherein the constriction member comprises a hydraulic constriction member and the adjustment device comprises a pump hydraulically connected to the hydraulic constriction member.

13. An apparatus according to any of claims 1-12, wherein the adjustment device comprises a powered adjustment device and further comprising an implantable energy transforming device (16) adapted to transform wireless energy emitted from outside the patients body into an energy form suited for powering the adjustment device.

14. An apparatus according to any of claims 1-13, further comprising a wireless remote control (15) for controlling the adjustment device (5) to adjust the constriction device to change the size of the stoma opening.

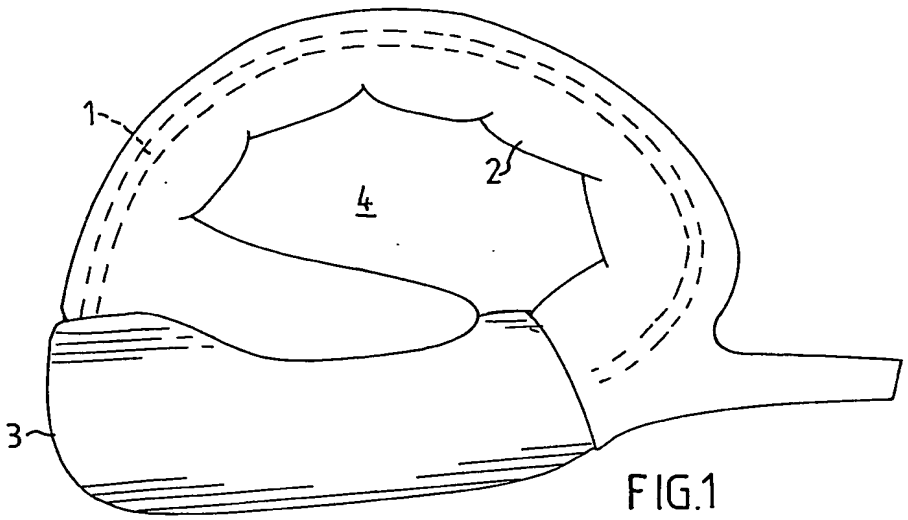


FIG.1

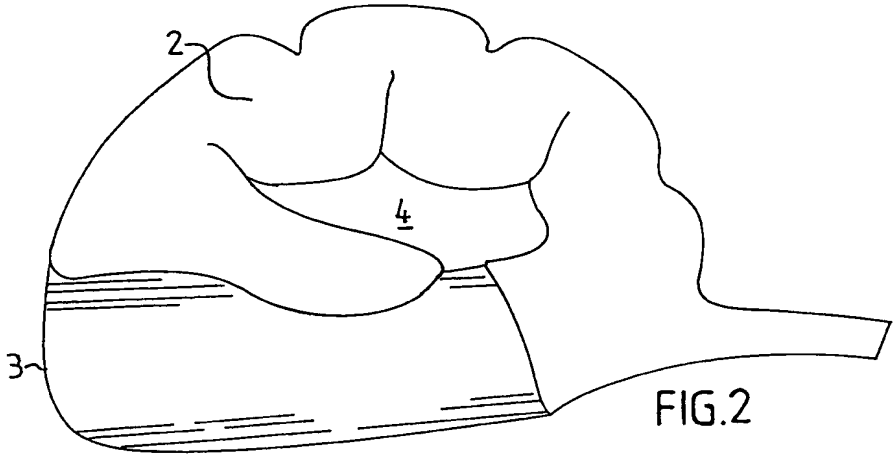


FIG.2

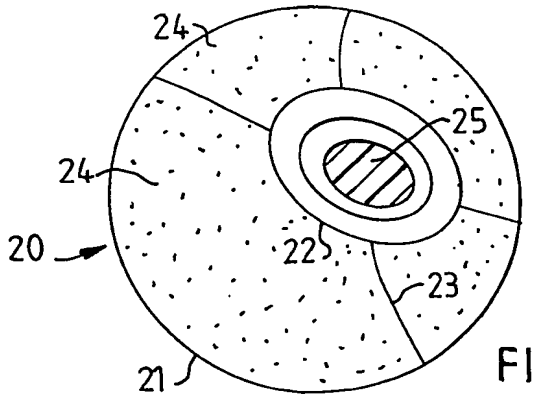


FIG.5

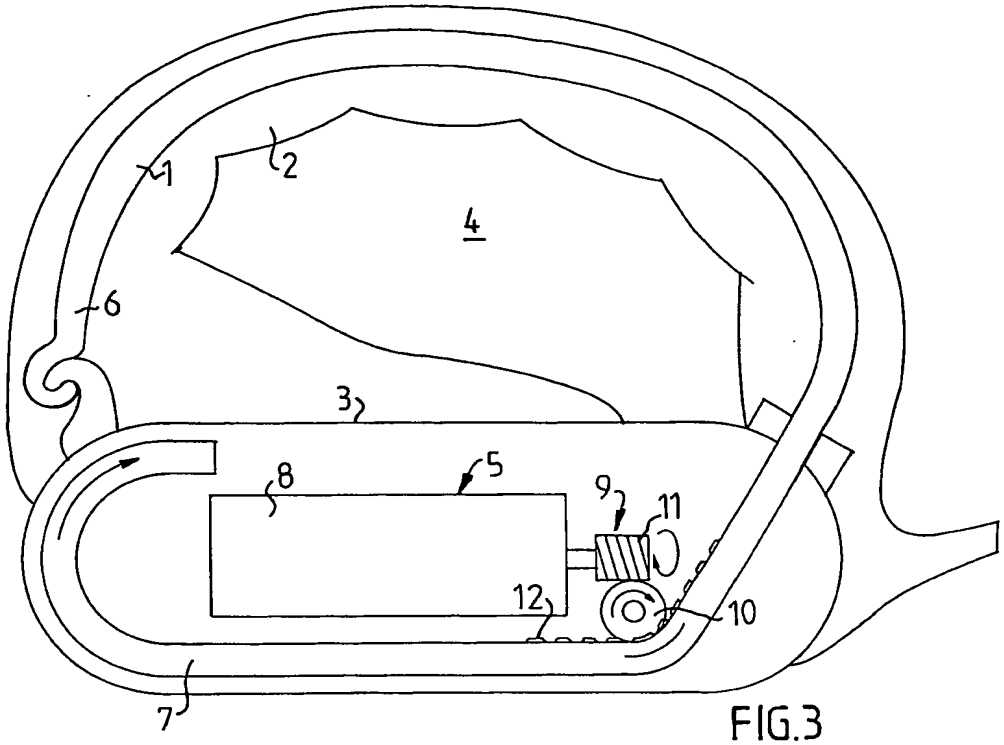


FIG.3

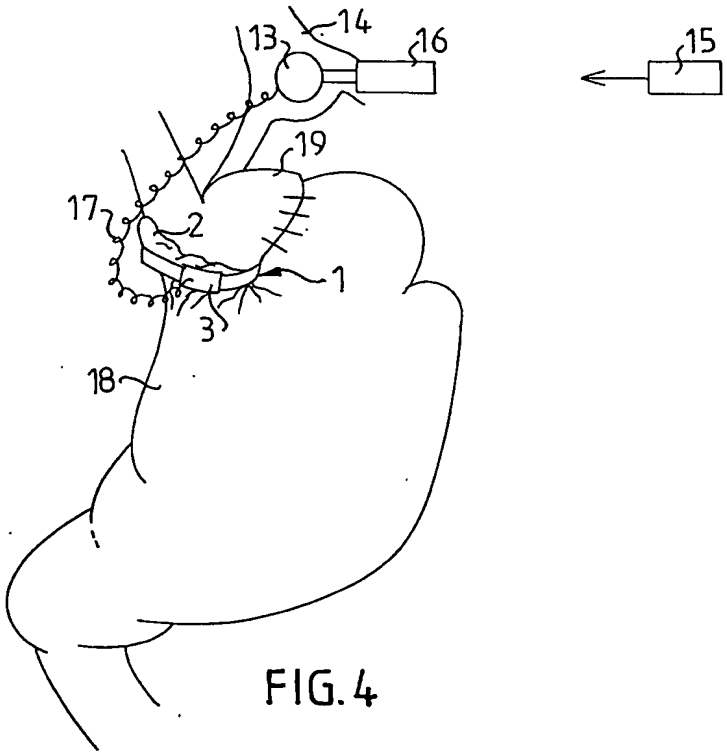


FIG.4